

### **REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

#### ***Status of the Claims***

The Office Action Summary Page indicates that claims 1-10 are currently pending in the present application. The Office Action is non-final. Claims 1, 3 and 7-10 have been amended to further clarify and define the invention. Support for “organic” compounds within claims 1, 3, 9 and 10 can be found in the present specification at page 6, second paragraph. Support for “substantially amorphous” in amended claims 1, 3 and 7-10 can be found on page 3, second paragraph, of the present specification.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

#### ***Issue Regarding the Abstract***

The Examiner indicates on page 3 of the Office Action that the present application does not contain an abstract of the disclosure as required by 37 C.F.R. § 1.72(b), and that an abstract on a separate sheet is required. The present application is a U.S. national stage application of PCT/EP2004/052421 which was filed on October 4, 2004 and has the international publication

number WO 2005/037424. Applicants have amended the present Application to insert the abstract from the published international application.

***Issues Under 35 U.S.C §112, Second Paragraph, Indefiniteness***

Claims 1-10 stand rejected under 35 U.S.C. §112, second paragraph. The Examiner asserts that the claims are vague and indefinite as set forth on pages 6-7 of the Office Action. Applicants respectfully traverse this rejection.

Although Applicants disagree with the Examiner's assertions, Applicants amended the claims, without prejudice or disclaimer of the subject matter contained therein, in the following manner.

Applicants have clarified the claims by removing the terms "apparatus" and "characterized in that" from claim 1. Also, Applicants have removed the phrase "the solutions of amorphous compounds or solvates having, at the same temperature, a higher content of crystallizing compounds than is achievable with a corresponding crystalline compound" from amended claims 1, 9 and 10.

Further, the terms "...substantially only the amorphous form..." have been replaced in amended claims 1, 9 and 10 by "...only the substantially amorphous form...." Applicants note that the present specification explains in detail on page 3, second paragraph, what is meant by "substantially amorphous." As the specification indicates, a substantially amorphous form may contain up to 20% by weight, particularly preferably only up to 2% by weight of crystalline phases and may mean a mesomorphic form.

Concerning the Examiner's assertion that claim 1 is "vague and indefinite" on the basis that it does not include "specific methodology steps," Applicants respectfully point out that method steps are indicated within the claims. For example, serial investigations are performed in parallel vessels under different conditions, and the polymorphic or pseudopolymorphic forms of a solid are identified after "organic compounds...are treated in the presence of identical or different solvents or solvent mixtures under identical or different physical conditions and optionally with salt, solvate or hydrate formation or formation of cocrystalline compounds or solid solutions until a phase equilibrium is established...." Applicants also submit that the phrase "organic compounds...are treated in the presence of identical or different solvents or solvent mixtures under identical or different physical conditions and optionally with salt, solvate or hydrate formation or formation of cocrystalline compounds or solid solutions until a phase equilibrium is established...." is the general feature that covers the different embodiments for the process of the invention set forth in the specification (see the present specification from page 6, fourth paragraph, to page 9, first paragraph).

Finally, Applicants submit that amended claims 9 and 10 specify that the arrangement and the apparatus are "for performing the process of claim 1." Contrary to the Examiner's assertion, the features listed in claim 10, namely items a), b), c) and the feature coming after "wherein," are apparatus features.

In view of the above, Applicants contend that the amended claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Issue Under 35 U.S.C. § 102(b), Anticipation***

Claims 1-10 stand rejected under 35 U.S.C. § 102(b) as anticipated by Blatter *et al.*, WO 03/026797 A2 (hereinafter “WO ‘6797”), Levinson *et al.*, WO 01/51919 A2 (hereinafter “WO ‘1919”), Stahly *et al.*, WO 02/052919 A2 (hereinafter “WO ‘2919”) and Hilfiker *et al.*, “*Polymorphism-Integrated Approach from High-Throughput Screening to Crystallization Optimization*,” Journal of Thermal Analysis and Calorimetry, Vol. 73, pp. 429-440 (2003) (hereinafter “Hilfiker”). Applicants respectfully traverse this rejection.

The Examiner asserts that WO ‘6797, WO ‘1919, WO ‘2919 and Hilfiker anticipate the claimed subject matter on the basis that they teach “the use of solvents and amorphous forms (*e.g.*, saturated and supersaturated solutions) among the possible starting solutions for the soluble form.”

Applicants disagree and believe that the Examiner’s interpretation of the reference teachings is incorrect.

WO ‘1919, which is discussed in the present application in the paragraph bridging pages 1-2, relates to a high-throughput method of formation, systematic analysis and identification of crystalline, amorphous and other forms of substances, including chemical compounds. This method comprises distributing a solid form of the compound of interest into an array, each element of the array being prepared from different solvent and additive combinations with different processing histories. WO ‘1919 does not specify the solid form of the substance of interest to be distributed. Applicants submit that the only specifically disclosed embodiment of the reference invention uses

glycine as the starting material (*See* WO '1919, section 7 - Example, pages 72-79). Since the solid state of the glycine used is not specified, it is expected to be in the form of monoclinic crystals which is usually available from commercial sources (Sigma, Aldrich) and as taught by The Merck Index.

WO '2919, which is also discussed in the paragraph bridging pages 1-2 of the present application, relates to a method of searching solid forms and screening a sample according to its forms. Applicants submit that WO '2919 does not specify the solid form of the substance used as starting material and does not give any hint that the amorphous form may be suitable. In the Examples (*See* WO '2919, pages 21-23), 4-(6-methoxy-2-naphthyl)-butan-2-one (Nabumeton) and sulfathiazole are used as starting materials, however, the source of those materials is not disclosed. Applicants contend that these substances are known to be usually available in a crystalline form from commercial sources and as taught by The Merck Index.

WO '6797 relates to a sealing system with flow channels and illustrates how this sealing system works for polymorphism screening using carbamazepine and different hydrates and solvates of carbamazepines as starting materials (*See* WO '6797, Examples 1 and 2, respectively). Applicants submit that carbamazepine is known to be usually available in a crystalline form from commercial sources and as taught by The Merck Index.

Hilfiker discloses a high-throughput polymorphism screening method using as an example, carbamazepine, as a starting material, which Applicants submit is a substance known to be usually available in a crystalline form from commercial sources and as taught by The Merck Index.

The above references neither disclose, nor suggest using only amorphous forms as starting

materials in a polymorphism screening method.

Because “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference,” the cited references cannot be a basis for a rejection under § 102(b). *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131 – To Anticipate a Claim, the Reference Must Teach Every Element of the Claim.

Therefore, Applicants respectfully submit that based on the above, the cited references do not anticipate the present invention.

### **CONCLUSION**

Applicants respectfully submit that the rejections raised by the Examiner have been overcome, and that the present application now stands in condition for allowance.

Should there be any outstanding matters that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla at the telephone number below, in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 23-0975 for any additional fees required under 37.C.F.R. §§1.16 or 1.17.

Respectfully submitted,

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